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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,414	07/29/2003	Paul Barnett	58771.000043	6305
<div>7590 12/30/2009</div> <div>Robert M. Schulman, Esq. Hunton & Williams 1900 K Street, N.W. Washington, DC 20006-1109</div>				
EXAMINER				
HILL, MYRON G				
ART UNIT		PAPER NUMBER		
1648				
MAIL DATE		DELIVERY MODE		
12/30/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/628,414

Applicant(s)

BARNETT ET AL.

Examiner

MYRON G. HILL

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48, 51 and 55 is/are pending in the application.
- 4a) Of the above claim(s) 35-42 and 46-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34, 43-45, 51 and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to the papers filed 9/25/09.

Claims 1-34, 43-45, 51 and 55 are under consideration.

Rejection Maintained

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-34, 43-45, 51 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ganne (US 6251407) in view of Salt *et al.* and Grimes *et al.* (US 2002/0058040).

The reference Barnett *et al.* has been changed to Salt *et al.* (Barnett is a coauthor). Salt *et al.* was cited on the last PTO-892 and the passages referred to by Applicant and the Office are that of Salt *et al.* and this merely clarifies the record and does not change the rejection.

Applicant argues that the cited references do not disclose motivation to make a composition in frozen layers, that the cited references do not teach all the limitations of the claims, that the layered composition had an unexpected property using the components of Ganne, and that a new form of a compound may be nonobvious.

Applicant also argues that pages 21-25 show the unexpected result of the layered vaccine to frozen emulsion of the same components.

Applicant's arguments have been fully considered and not found persuasive.

Applicant's argument of unexpected results is not persuasive because Salt *et al.* teach that ultra-low temperature FMDV antigen is storage stable.

Grimes *et al.* teach it was surprising to discover that adjuvant can be frozen and retain the adjuvant properties (paragraph 43) and used ISA. Applicant argues that this result was with emulsified ISA but this shows the product can be frozen and still retain adjuvant effectiveness.

Applicant's argument about Salt *et al.* and that the antigen may or may not be frozen is not persuasive because lacking evidence to the contrary, ultra-low temperature is considered frozen.

While the words quoted appear on page 24, the results shown do not correspond to the words. The results of 7 months are found on the table on page 23 and that is between layered and placebo formulations not conventional frozen emulsion. The Tables on pages 23 and 25 do not seem to contain the comparison either.

Applicant's comments concerning *in re Berry* are considered and the product made is different because it is a different crystal structure. Applicant has not shown that the frozen components are different when frozen or that the thawed product is different from the starting components.

Thus, the rejection is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MYRON G. HILL whose telephone number is (571)272-0901. The examiner can normally be reached on M-Th and flex.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. G. H./
Examiner, Art Unit 1648

/A R Salimi/
Primary Examiner, Art Unit 1648